Verrica Pharmaceuticals Receives Complete Response Letter from the FDA for its New Drug Application for VP-102 for the Treatment of Molluscum Contagiosum

July 14, 2020

– Complete Response Letter Requests Additional Chemistry, Manufacturing, and Controls (CMC) and Human Factors Information –

– No Clinical Safety or Efficacy Issues Identified –

– Conference Call and Webcast Today at 8:30 a.m. ET –

WEST CHESTER, Pa., July 14, 2020 (GLOBE NEWSWIRE) -- Verrica Pharmaceuticals Inc. (“Verrica”) (Nasdaq: VRCA), a dermatology therapeutics company developing medications for viral skin diseases requiring medical interventions, today announced that the U.S. Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) regarding the New Drug Application (NDA) for VP-102, the Company’s investigational, proprietary, drug-device combination for the treatment of molluscum contagiosum (molluscum). The Company had previously disclosed receipt of a letter from the FDA in which the agency noted deficiencies that precluded discussion of labeling and post-marketing requirements/commitments.

According to the CRL, the FDA is seeking additional information regarding certain aspects of the CMC (Chemistry, Manufacturing, and Controls) process for the drug/device combination, as well as Human Factors validation. Importantly, the FDA did not identify any clinical deficiencies. The Company plans to request a Type A meeting to discuss the issues that were described in the CRL and other matters pertaining to the steps required for the resubmission of the NDA for VP-102.

“We are confident that we can work closely with the FDA to fully address the issues raised in the letter and we continue to believe VP-102 remains viable for FDA approval,” said Ted White, President and Chief Executive Officer, Verrica. “We are unwavering in our commitment to the millions of patients and families with molluscum, and are dedicated to ultimately gaining FDA approval of VP-102. We look forward to providing updates on our progress toward resubmitting our NDA for VP-102 as quickly as possible.”

Verrica believes that the positive results from its two double-blind Phase 3 trials (CAMP-1 and CAMP-2), which evaluated VP-102 compared to placebo in patients two years of age and older diagnosed with molluscum, have demonstrated favorable safety, efficacy and tolerability. Specific results from the CAMP-1 and CAMP-2 studies showed that 46 and 54 percent, respectively, of subjects treated with VP-102 achieved complete clearance of all baseline and new molluscum lesions at the end of the trials (Day 84), versus 18 and 13 percent, respectively, of subjects in the vehicle groups ($p<0.0001$). There were no serious adverse events reported in VP-102-treated subjects, and most adverse events reported in subjects receiving VP-102 were local skin reactions and mild to moderate in severity.

The Company believes its existing cash, cash equivalents, and marketable securities, which totaled approximately $80 million as of June 30, 2020, will be sufficient to support planned operations at least through the fourth quarter of 2021. The foregoing amount of cash, cash equivalents and marketable securities is preliminary, is subject to change based on the completion of the Company’s quarter-end review process, and includes calculations or figures that have been prepared internally by management and have not been reviewed or audited by the Company’s auditors.

Conference Call and Webcast

Verrica will host a conference call and webcast today, July 14, 2020, at 8:30 a.m. ET. The conference call can be accessed by dialing (866) 688-9534 for domestic callers or (409) 216-0837 for international callers. Please provide the operator with the conference ID 9937817 to join the conference call. The conference call will be available via webcast under the Investor Relations section of Verrica's website at www.verrica.com. An archive of today's teleconference and webcast will be available on Verrica's website for 60 days following the call.

About Verrica Pharmaceuticals Inc.

Verrica is a dermatology therapeutics company developing medications for viral skin diseases requiring medical interventions. The Company’s late-stage product candidate, VP-102, is a potential first-in-class topical therapy for the treatment of molluscum contagiosum. Verrica submitted an NDA for VP-102 for the treatment of molluscum in September 2019. A Complete Response Letter was received from the FDA regarding the NDA for VP-102 on July 13, 2020. If approved, VP-102 will be marketed in the United States under the conditionally accepted brand name YCANTH™. In addition, Verrica has successfully completed a Phase 2 study of VP-102 for the treatment of common warts and is currently conducting a Phase 2 study of VP-102 for the treatment of external genital warts. The Company is also developing VP-103, its second cantharidin-based product candidate, for the treatment of plantar warts. For more information, visit www.verrica.com.

Forward-Looking Statement

Any statements contained in this press release that do not describe historical facts may constitute forward-looking statements as that term is defined in

the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as “believe,” “expect,” “may,” “plan,” “potential,” “will,” and similar expressions, and are based on Verrica’s current beliefs and expectations. These forward-looking statements include expectations regarding the Company’s expectations with regard to its interactions and communications with the FDA, including its expectation to discuss with the FDA regarding the issues raised in the CRL and the Company’s plans to address them, the Company’s future resubmission of the NDA for VP-102 for the treatment of molluscum, the potential approval of the NDA for VP-102 following resubmission, the potential benefits and potential approval and commercialization of VP-102 for the treatment of molluscum, the Company’s plans with respect to planned clinical trials of VP-102 for common warts and VP-103 for plantar warts, and the Company’s expectations with respect to its cash reach. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the drug development process and the regulatory approval process, Verrica’s reliance on third parties over which it may not always have full control, uncertainties related to the COVID-19 pandemic and other risks and uncertainties that are described in Verrica’s Annual Report on Form 10-K for the year ended December 31, 2019, Verrica’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, and other filings Verrica makes with the U.S. Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and are based on information available to Verrica as of the date of this release, and Verrica assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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